CDC VISI Industry Forum
Meeting Minutes from June 15, 2001

Participating Organizations

- Aventis Pasteur
- Chiron
- Glaxo Smith Kline
- Merck
- Wyeth-Lederle

Meeting Objective

- Provide prospective vendors with project specifications and scope.
- Develop time lines and tasks for project completion.

CDC Objective

- Improve the compliance and accuracy associated with vaccine information entry. Automate the process to limit the opportunity for human error in the process of recording information.
- Provide for the capability to initiate a National database for all patients receiving vaccines.

CDC VISI Proposed Guideline

- See summary attachment based on CDC VISI draft guidelines as of April 2001 - http://www.cdc.gov/nip/visi/prototypes.htm.

Industry Recommendations from April 2001 Meeting.

- Adopt a three-phased approach to implement methods for improved data transfer.
    - Phase 1; Implement a single detachable label for single dose presentations that includes only the human readable required information (Generic name, Lot #, and Manufacturer). Move to multidose presentations after single dose is completed.
    - Phase 2; Form an industry working group to meet with government agencies and user groups. The group to explore the available technologies, make recommendations based on cost/benefit and appropriate technology and develop a fully automatic data transfer system.
    - Phase 3; Implement fully automatic data transfer system

Meeting Summary

- Prospective vendors attending the meeting were:
    - Dave Cobb, Director Business Development – Safety syringes, Inc. email: dcobb@safetysyringes.com
    - Randall Kemmerer, Director Business Development – Acuity CiMatrix. Email: Rkemmerer@acut.com
    - Richard P. Fox, Jr, President/CEO – Fox IV Technologies, Inc. email: foxiv@foxiv.com
    - Michael Montalbano, Account Manager – Saddle Brook Controls. Email: mikem@saddlebrookcontrols.com
    - Robert Conrad, Area Sales Manager – Saddle Brook Controls. Email: Sbcmidatl@home.com
    - Rick Schuessler, Senior Director Engineering – Symbol Technologies, Inc. Email: rick@symbol.com
    - Jerome J. Bobinski, Sr. Healthcare Manager – Symbol Technologies, Inc. Email: bobinski@symbol.com

    - Not Present- Peter Siedl – Schriener Labels Inc. Email: held@schreiner-etiketten.de
- Future meeting schedule for the industry sub committee was agreed to be as follows:
    - July 12, 2001 (Glaxo Smith Kline) Philadelphia PA. Vendor presentations.
        - Each vendor to have 1 hr to present their technology for achieving CDC objectives and Industry specifications.

        - There will be a 15 minute question and answer period after each presentation.
        - Meeting to start at 9AM.
        - T. Calabrese to provide directions and lodging information.
    - July 13, 2001 (Glaxo Smith Kline) Philadelphia PA. Industry Sub committee meeting to review vendor data and narrow potential choices.
    - September 7, 2001 (Merck) West Point PA. Industry Sub committee meeting to collate company review data with vendor data and prepare final recommendations for the CDC-VISI general meeting.
- It was agreed to prepare a checklist for evaluating vendor presentations. (Wyeth)
- The current project specification was provided to all vendors. Discussions focused on the following:
    - Data:
        - Coded information to include:
            - NDC# - 10 characters
            - Lot # - 10 characters
            - Exp. Date – 6 characters
            - UCC Identifiers if required – 4 characters
            - Optional information – nice to have but not required include 1) site of administration and 2) Person administering the product.
        - Human readable information to include:
            - Manufacturer
            - Generic name of the product
            - NDC#
            - Lot #
            - Expiration Date
            - Optional information – nice to have but not required include 1) site of administration and 2) Person administering the product.
    - Looking for on-line data verification.
    - Methodologies.
        - RSS-14 composite
        - EAN128
        - Data Matrix

        - Smart Label
        - Multiple Detach
        - Other
    - Solution must be FDA acceptable.
- Manufacturers to provide sample of label printing – preferably worst case – for detachable label with 3X detachables per dose to each of the vendors listed above. This sample to be provided electronically by 6/25/2001.
- Industry is seeking a "turn-key" solution including end customer hardware and software availability.
- Additional technologies, solutions or partnerships are welcomed.
- Time line proposed:
    - Presentation to CDC and FDA in Fall 2001.
    - Development of company specific specifications and quotations by end of Q2, 2002
    - Presentations and individual company financial approvals for the 2003 budgetary years by end of 2002.
    - Integration into production lines in 2003-2004
    - Validation and FDA approval in 2004.
    - Potential market availability in 2005.

Next Steps

- Provide minutes of the meeting from June 15, 2001. (R. Filipski by June 22, 2001)
- Forum participants to review and comment on minutes by June 29, 2001. (All Participants)
- Provide CDC with final minutes of the Industry Forum minutes from June 15, 2001. (R. Filipski by June 22, 2001)
- Develop vendor review check sheet by July 6, 2001 and circulate to the committee (J. Barry & S. Fans)
- Send sample of label printing – preferably worst case – for detachable label with 3X detachables per dose to each of the vendors listed above. This sample to be provided electronically by 6/25/2001. (All Manufacturers)